II. REMARKS AND ARGUMENTS

A. Status of the Claims

Claims 1-13 are pending. Claims 14-81 have been cancelled without prejudice.

B. Rejection under 35 U.S.C. § 112

In the office action, the Examiner rejected claims 1 and 3-10 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner stated that "while the specification have identified particular amino acids which are present in such a channel in several bacteria, the specification has not provided a description of an adequate number of species encompassed by the claims, especially since one cannot envision which fragments or portions of an intact RNAP would encompass the exit channel amino acid sequence…one skilled in the art would conclude that the disclosure of intact RNAP RNA exit channel is not representative of the undefined genus of derivatives and fragments recited in the claims" (Office Action, page 2-3).

Applicants respectfully traverse the rejection. The written description requirement of 35 USC 112, first paragraph, is fulfilled when the patent specification described the claimed invention in sufficient detail such that the claim limitations are described so that one skilled in the art would recognize that the applicants had invented the subject matter. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), *In re Herschler*, 591 F.2d 693, 700 (CCPA 1979).

The present invention is directed to methods for identifying agents that bind to a bacterial RNAP through interactions with a bacterial RNAP homologous RNA-exit-channel amino-acid sequence: i.e., the target region.

In one embodiment, the present invention is directed to comparing the binding of a compound to a "first entity" that contains the target (test entity) and to a "second entity" that contains an altered target (control entity). This comparison clearly, unambiguously, enables specific identification of compounds that function through interactions with the target.

At the time of the present invention, as disclosed in the specification, the Applicants were clearly in possession of the invention as applied to intact RNAP and fragments of RNAP suitable for use as "first entities" (test entities), and as applied to both derivatives of intact RNAP and fragments of RNAP suitable for use as "second identities" (control entities).

Foremost, the instant target is defined clearly in the specification (as acknowledged by the Examiner). The instant target is defined as "a region within the bacterial RNAP RNA-exit-channel comprising residues corresponding to, and alignable with, for example, 1251, 1256, and 1321 (See also pages 9-12 of the specification) of the beta subunit of RNAP from Escherichia coli and residues 248-249 of the beta' subunit of RNAP from Escherichia coli (the 'homologous RNA-exit-channel amino-acid sequence' or 'target'; Figure 1)."

A fragment of a bacterial RNAP suitable for this invention is merely a part of a bacterial RNAP that is less than an intact bacterial RNAP and that includes the homologous RNA-exit-channel amino-acid sequence. Such fragments of RNAP were clearly envisioned and well within the possession of one skilled in the art as of the time of the invention. Such fragments of RNAP can include fragments of RNAP that contain truncations of one or more RNAP subunit or deletions in one or more RNAP subunit, which were clearly possessed by the skilled artisan as of the time of the invention.

Moreover, many such fragments of bacterial RNAP are known in the art. The literature reports numerous examples of such fragments of RNAP that contain truncations of one or more

RNAP subunit or deletions in one or more RNAP subunit, as described, for example, in the following:

Igarashi K et al.; Cell; Vol. 65; No. 6, pp. 1015-22, (1991). "Bipartite functional map of the E. coli RNA polymerase alpha subunit: involvement of the C-terminal region in transcription activation by cAMP-CRP." (See attached)

Severinov et al., J Biol Chem. Vol. 269, No. 19, pp. 14264-9 (1994) "A non-essential domain of Escherichia coli RNA polymerase required for the action of the termination factor Alc." (See attached)

Tang et al., Proc Natl Acad Sci U S A; Vol. 92; No. 11, pp. 4902-6 (1995)."Rapid RNA polymerase genetics: one-day, no-column preparation of reconstituted recombinant Escherichia coli RNA polymerase." (See attached)

Kuznedelov et al., EMBO J., Vol. 21, no. 6; pp. 1369-78 (2002) "Structure-based analysis of RNA polymerase function: the largest subunit's rudder contributes critically to elongation complex stability and is not involved in the maintenance of RNA-DNA hybrid length." (See attached)

Kuznedelov et al., Methods Enzymol., Vol. 370; pp.94-108 (2003) "Preparation and characterization of recombinant Thermus aquaticus RNA polymerase." (See attached)

King et al., J Mol Biol., vol. 342, No. 4, pp. 1143-54 (2004) "A conserved zinc binding domain in the largest subunit of DNA-dependent RNA polymerase modulates intrinsic transcription termination and antitermination but does not stabilize the elongation complex." (See attached)

Applicants submit that persons skilled in the art are aware of this literature and know how to produce and analyze such fragments of bacterial RNAP.

In view of the arguments presented above, Applicants respectfully submit that proper written description for claims 1 and 3-10 is provided in the present specification. Therefore, Applicants respectfully request that the Examiner's rejection be removed.

Conclusion

This amendment is being submitted together with a petition for a three-month extension of time and a Notice of Appeal. The Commissioner for Patents is hereby authorized to charge the fee due for the petition for extension of time and Notice of Appeal to Deposit Account No. 50-0552.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted
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